

## REMARKS

### **1. Claim Status and Support**

Claims 9, 13, 14, 16, 46, 47, 57, and 61 as amended, and claims 59-60 are pending in the instant application. Claims 1-8, 10-12, 15, 17-45, 48-56, 58 and 62 have been cancelled without prejudice or disclaimer. The amendments to the claims are fully supported by the specification and the claims as originally filed. No new matter has been added as a result of the instant claim amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### **2. Rejections of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 112, first paragraph**

Claims 9, 13, 14, 16, 46, 47, 57, and 59-61 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 9, 13, 14, 16, 57, and 61 have been amended, thereby obviating the rejections.

The Action indicates that the phrase “an amino acid sequence” in the claims included “any sequence of two or more contiguous amino acids of that sequence.” To provide clarity, claims 9, 13, 14, and 16 have been amended to recite “*the* amino acid sequence” rather than “*an* amino acid sequence.”

The Action also indicates that the phrase “a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755” as recited in claim 13 includes a genus of “structurally and functionally different polypeptides” and that “there is no clear nexus between the amino acid sequence of SEQ ID NO:5 and the amino acid sequence of the Secs-1 polypeptide encoded by the DNA insert contained in ATCC Deposit No. PTA-1755.” We respectfully disagree and note that *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1325 (Fed. Cir. 2002) found that “reference in the specification to a deposit in a public depository, which makes its contents accessible to the public,” such as the ATCC “constitutes an adequate description of the deposited material sufficient to comply with the written description requirement.” However, in an effort to expedite allowance of the instant application, claims 13 and 16 have been amended to recite “a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, wherein the nucleic acid molecule encodes a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5.” Applicants reserve the right

to pursue broader claims directed to a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755 in a timely filed continuation or divisional application.

The Action further indicates that claim 14, which recites “a fragment of at least 25 amino acid residues of SEQ ID NO: 5,” could encompass a polypeptide that “does not necessarily bear any greater structural relationship to the polypeptide of SEQ ID NO: 5 or share any of its functions.” Claim 14 has been amended and no longer recites a fragment of SEQ ID NO: 5. Similarly, the Action rejects claim 57, and indicates that the “host cell to which the claims [are] directed need not comprise a vector comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO: 5” but could “merely comprise a region of such a nucleotide sequence.” Claim 57 has been amended and no longer recites fragments of SEQ ID NO: 5. Similar language has also been deleted from claim 61. Claims 46, 47, 59 and 60 are dependent on claims 9, 13, 14, or 57, and thus share the limitations of the newly amended claims.

Applicants, therefore, submit that the written description requirement is satisfied, and respectfully request withdrawal of all rejections made on this basis.

**3. Rejection of claims 46 and 47 under 35 U.S.C. § 112, first paragraph**

Claims 46 and 47 are rejected under 35 U.S.C. § 112, first paragraph, under the enablement requirement. The Action indicated that the claims are enabled for *isolated* fusion polypeptides. Claim 46 has been amended accordingly (*i.e.* by reciting “isolated”), thereby overcoming this ground of rejection. Applicants, therefore, submit that the enablement requirement is satisfied, and respectfully request that this ground of rejection be withdrawn.

**4. Rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 102(e)**

Claims 9, 13, 14, 16, 46, 47, 57, and 59-61 are rejected under 35 U.S.C. § 102(e) as anticipated by US Patent Application Publication No. 2002/0068319 A1 (Ni *et al.*).

As an initial matter, Ni *et al.* do not teach SEQ ID NO: 6, as recited in claim 14. As pointed out in the specification, SEQ ID NO: 6 is a mature Secs-1 polypeptide. Ni *et al.* never provided any specific details about the mature form of SEQ ID NO: 96, and instead provided only very general disclosure about mature form that could exist. Such disclosure is not specific, and never suggests a particular mature form of the polypeptides disclosed in the application. According to M.P.E.P. § 2131, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either

expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Consequently, Ni *et al.* cannot anticipate the instant claims, because Ni *et al.* do not actually teach the mature polypeptide sequence of Secs-1 (*i.e.* SEQ ID NO: 6).

With regard to claims 9, 13, 14, 16, 46, 47, 57, and 59-61, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 establishing invention of the subject matter of the claims rejected under 35 U.S.C. § 102(e) prior to the effective date of the reference on which the rejection is based. Applicants contend that the attached Declaration Pursuant to 37 C.F.R. § 1.131, is sufficient to overcome the rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 102(e) as being anticipated by Ni *et al.* While the polypeptide sequence disclosed by Ni *et al.* was disclosed in the sequence listing of U.S. Patent Application Publication No. 2002/0068319 A1, which claims the benefit to U.S. Provisional Application No. 60/155,709, filed September 24, 1999, Applicants contend that the document accompanying the Declaration sufficiently asserts a reduction to practice of the claimed invention before September 24, 1999. Specifically, paragraph 4 of the Declaration states that:

Accompanying this Declaration is a copy of a sequence match obtained by us before September 24, 1999 documenting a reduction to practice of our invention. This match was obtained following a comparison of a nucleic acid sequence derived from the amino acid sequence of a secreted polypeptide isolated from squamous cell and colorectal carcinoma cells to a propriety EST database.

The specification states (page 85, line 23-28) that:

Using a proteomic-based approach, a novel protein was isolated from conditioned media obtained from squamous cell and colorectal carcinoma cell lines. The approach utilized in isolating this protein suggests that it is a naturally secreted product. The amino acid sequence of the isolated protein was determined and found to share sequence identity with EST sequences present in both GenBank and proprietary (Amgen dbEST) database.

Applicants contend that when the nucleic acid sequence corresponding to the polypeptide sequence set forth in SEQ ID NO: 5 was obtained, the claimed invention was reduced to practice. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1991). As described in the Declaration, and in the specification, the nucleic acid sequence was obtained when a comparison of the amino acid sequence derived from a protein obtained from a squamous cell and colorectal carcinoma cell lines was compared with a propriety EST database. The sequence match

accompanying the Declaration establishes that Applicants identified and possessed the nucleotide sequence of the claimed invention, and therefore, possessed the amino acid sequence encoded by the nucleotide. Thus the Applicants had reduced the claimed invention to practice before September 24, 1999. Applicants, therefore, contend that Ni *et al.* does not anticipate claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 102(e), and therefore, respectfully request that this rejection be withdrawn.

**5. Rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 103(a)**

Claims 14, 57, and 59-61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0068319 A1 (Ni *et al.*). The rejection to Claim 14, 57, and 61 appears to be based on the following language recited in the claims, "a fragment of at least 25 amino acid residues, but no more than 80 amino acid residues, of the amino acid sequence set forth in SEQ ID NO: 5". This language has been canceled from claim 14, 57, and 61 as discussed above, obviating the current rejection. Claims 59 and 60 are dependent on claim 57, and thus the rejection of these claims is also obviated by the instant claim amendments. In addition, the Declaration under 37 C.F.R. § 1.131 enclosed herewith, establishing invention of the subject matter of the claims rejected under 35 U.S.C. § 103(a) prior to the effective date of the reference on which the rejection is based. Applicants contend that the Declaration Pursuant to 37 C.F.R. § 1.131, is sufficient to overcome the rejection of claims 14, 57, and 59-61 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2002/0068319 A1 (Ni *et al.*) for the reasons noted above. Therefore, the rejections as to these claims have also been obviated. Applicants respectfully request that this rejection be withdrawn.

**CONCLUSION**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Rawlings believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,  
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Dated: March 29, 2007

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